

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	DENTURE ADHESIVE CREAM
Registration number	-
Synonyms	DENTURE FIXATIVE * POLIDENT DENTURE ADHESIVE * SUPER POLIGRIP ORIGINAL DENTURE ADHESIVE CREAM * POLIGRIP/COREGA DENTURE ADHESIVE CREAM * SUPER POLIGRIP LOW GANTREZ DENTURE ADHESIVE CREAM * MFC 50937 * MFC 50880 * MFC 50885 * MFC 50886 * ULTRA POLIGRIP REGULAR (CANADA) * FORMULA NUMBER IB1380 * ULTRA POLIGRIP, DENTURE ADHESIVE CREAM * ULTRA POLIGRIP DENTURE FIXATIVE * FORMULA IB1544 * POLIGRIP ULTRA FRESH, DENTURE ADHESIVE CREAM FIXATIVE * POLIGRIP TOTAL CARE (UK) * DENTURE ADHESIVE CREAM FIXATIVE * FORMULA IB1649 * COREGA FREE, DENTURE ADHESIVE CREAM * FORMULA IB1688 * COREGA FRESH, DENTURE ADHESIVE CREAM * COREGA FRESH DENTURE FIXATIVE * FORMULA IB1689 * COREGA CREAM, DENTURE ADHESIVE CREAM * COREGA CREAM DENTURE FIXATIVE * FORMULA IB1690 * POLIGRIP ULTRA FRESH, DENTURE ADHESIVE CREAM * POLIGRIP ULTRA FRESH DENTURE FIXATIVE * FORMULA IB1742 * DENTURE ADHESIVE CREAM DENTURE FIXATIVE * FORMULA IB1967 * POLIGRIP FRESH GEL, DENTURE ADHESIVE CREAM * POLIGRIP FRESH GEL DENTURE FIXATIVE * FORMULA IB2115 * PROJECT DOUBLE * DENTURE ADHESIVE FIXATIVE, FORMULATED PRODUCT
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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Cosmetic Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.3. Other hazards

Assume that this product is capable of sustaining combustion.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHARMACEUTICAL GRADE PETROLATUM	25,0 - 30,0	8009-03-8 232-373-2	-	649-254-00-X	
Classification:	DSD: -				N
	CLP: -				N
LIGHT MINERAL OIL	15,0 - 30,0	8042-47-5 232-455-8	-	-	
Classification:	DSD: -				
	CLP: -				
SODIUM CARBOXYMETHYL CELLULOSE	0 - 34,0	9004-32-4 -	-	-	
Classification:	DSD: -				
	CLP: -				
MALEIC ACID, POLYMER WITH METHYL VINYL ETHER	0 - 30,0	25153-40-6 -	-	-	
Classification:	DSD: -				
	CLP: -				
METHYL VINYL ETHER-MALEIC ANHYDRIDE COPOLYMER	0 - 30,0	9011-16-9 -	-	-	
Classification:	DSD: -				
	CLP: -				
CARBOXYMETHYLCELLULOSE	0 - 24,0	9000-11-7 -	-	-	
Classification:	DSD: -				
	CLP: -				
OIL OF SPEARMINT	0 - 1,0	8008-79-5 -	-	-	
Classification:	DSD: R10, Xn;R22-65, Xi;R36/38, R43, N;R51/53				
	CLP: Flam. Liq. 3;H226, Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411				

Other components below reportable levels 0 - <7,0

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

SECTION 4: First aid measures

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

4.2. Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards

Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures

In the event of fire, cool tanks with water spray. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

Specific methods

Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Dike far ahead of spill for later disposal. Use water spray to reduce vapours or divert vapour cloud drift. Following product recovery, flush area with water.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged or repeated contact with skin. Avoid prolonged exposure. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s)

Cosmetic Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components

	Type	Value	Note
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)	OHC	1	
GANTREZ-77 (DOUBLE SALT) (CAS 62386-95-2)	OHC	1	1000-5000 mcg/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Chemical goggles are recommended. (eg. EN 166)

Skin protection

- **Hand protection** For prolonged or repeated skin contact use suitable protective gloves.

- **Other** Wear suitable protective clothing.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.

Form Cream.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Solubility (other) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Explosive properties Not available.

Oxidizing properties Not available.

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity Not available.

10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	Not available.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.

Symptoms Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Components	Species	Test results
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)		
Acute		
<i>Oral</i>		
LD	Rat	> 5 g/kg
LIGHT MINERAL OIL (CAS 8042-47-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
OIL OF SPEARMINT (CAS 8008-79-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 15 g/kg
Chronic		
<i>Oral</i>		
NOAEL	Rat	>= 3000 mg/kg, 2 years

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory sensitisation	Not available.
Skin sensitisation	This product is not expected to cause skin sensitisation.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day 2 year bioassay, oral administration Result: NOAEL Species: Rat Dermal application Result: negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

LIGHT MINERAL OIL (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
Aspiration hazard	Not likely, due to the form of the product.
Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test results
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	100 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 20000 mg/l, 96 hours Static test
SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	100 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 20000 mg/l, 96 hours Static test

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-life (Photolysis-atmospheric)

LIGHT MINERAL OIL < 1 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CARBOXYMETHYLCELLULOSE 7 %, 28 days Zahn-Wellens, Activated sludge

SODIUM CARBOXYMETHYL CELLULOSE 7 %, 28 days Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

LIGHT MINERAL OIL 24 %, 28 days Modified Sturm test., Activated sludge

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 94/33/EC on the protection of young people at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R10 Flammable.
R22 Harmful if swallowed.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65 Harmful: may cause lung damage if swallowed.
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Synonyms

Training information

Follow training instructions when handling this material.

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.